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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,695	01/16/2004	Gerianne Tringali DiPiano	FEM 105	8448

23579 7590 12/01/2005

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EXAMINER
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AHMED, AAMER S

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 12/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/759,695	<b>Applicant(s)</b> DIPIANO ET AL.	
	<b>Examiner</b> Aamer S. Ahmed	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 January 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 August 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>8/19/04, 4/12/04</u>  | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION*****Drawings***

The drawings are objected to because lines 4-4 of Figure 4C are not shown. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Objections***

Claim 9 is objected to because of the following informalities: the phrase "diseases of the of the female" is incorrect. Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yeager et al ('573). Yeager describes an applicator comprising of a barrel 47, with a medication chamber 24; a plunger 98 with tip (see Figure 2), which is insertable in telescoping relation to the applicator barrel; a flange 64; a cap 12 which is removable and forms an air-tight seal with the barrel (column 3), as does the plunger (column 6).

Moreover, Yeager et al teaches a method of inserting the applicator barrel into a patient's vagina by removing the cap, depressing the plunger to administer the pharmaceutical formulation, in an amount effective to treat diseases of the female urogenital system; to the region of the patient's upper vaginal vault (column 2), the medicament in the form of a powder, gel, cream lotion, suppository, ovule, table or capsule (column 2).

Yeager fails to disclose that the medication chamber 24 is capable of containing 1 mL or less of pharmaceutical composition.

It would have been an obvious matter of design choice to make the medication chamber of Yeager ('573) capable of containing 1 mL or less of pharmaceutical composition, since such a modification would have involved a mere change in size of a component and in order to achieve a more precise dose delivery. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Pat. No. 6776776	Alchas et al.
U.S. Pat. No. 3780735	Crouter et al.
U.S. Pat. No. 5462740	Evenstad et al.
U.S. Pat. No. 6364854	Ferrer et al.
U.S. Pat. No. 5387103	Fischer
U.S. Pat. No. 5697918	Fischer et al.
U.S. Pat. No. 5489266	Grimard
U.S. Pat. No. 6706728	Hedenstrom et al.
U.S. Pat. No. 5860946	Hofstatter
U.S. Pat. No. 3506008	Huck

U.S. Pat. No. 4636202	Lowin et al.
U.S. Pat. No. 4772274	Lukacs
U.S. Pat. No. 5843043	Markus
EP Pat. No. 263976	Okuda et al.
U.S. Pat. No. 5364363	Pearson et al.
U.S. Pat. No. 5397312	Rademaker et al.
U.S. Pat. No. 5681279	Roper et al.
U.S. Pat. No. 5201779	Shiao
U.S. Pat. No. 5531703	Skwarek et al
U.S. Pat. No. 5662601	Snead
U.S. Pat. No. 3667465	Voss
U.S. Pat. No. 4361150	Voss
U.S. Pat. No. 6692468	Waldenburg
U.S. Pat. No. 5213566	Weissenburger
U.S. Pat. No. 5330427	Weissenburger
U.S. Pat. No. 4620534	Zartman

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.

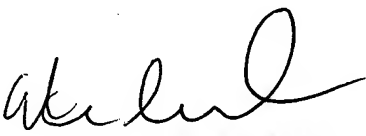
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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NICHOLAS D. LUCCHESI  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700